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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/591,789 06/12/00 MACHALONIS

J 7760-012

020583
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

HM12/1002

EXAMINER

PARKIN, J

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/591,789

Applicant(s)
Machalonis, J. J., et al.

Examiner
Jeffrey S. Parkin, Ph.D.

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 06/12/00

2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-5, drawn to a purified **peptide** or derivative thereof, classified in class 530, subclass 326.
- b. Group II, claim(s) 6, 7, 24, and 25, drawn to a **method** for **increasing Th₁ cytokine production**, classified in class 424, subclass 278.1.
- c. Group III, claim(s) 8-15, drawn to a **method** for **treating AIDS**, classified in class 424, subclass 208.1.
- d. Group IV, claim(s) 16 and 17, drawn to a **method** for **treating cardiovascular disorders**, classified in class 514, subclass 2.
- e. Group V, claim(s) 18 and 19, drawn to a **method** for **treating allergies**, classified in class 424, subclass 278.1.
- f. Group VI, claim(s) 20-22, drawn to a **method** for **treating cancer**, classified in class 435, subclass 7.23.
- g. Group VII, claim(s) 23, drawn to a **method** for **treating immunosuppression**, classified in class 424, subclass 278.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions II-VII are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified groups is directed toward a different scientific objective (e.g., treating AIDS, immune cancer, allergies) that employs different reagents and methodology steps. Therefore, each invention is clearly drawn toward a different inventive concept.

4. Inventions I and II-VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. ¶ 806.05(h)). In the instant case, the peptide of Group I can be employed in a number of materially different processes such as diagnostic methodologies or the preparation of immunological reagents.

5. Applicants are further advised that each of the peptides listed in the claims constitutes an independent and distinct invention. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified peptides has a different structure and attendant biochemical, immunological, and physical activities and properties. Moreover, separate searches will be required for each peptide. Therefore, each peptide is clearly drawn toward a different inventive concept.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, requirement for independent searches, and recognized divergent subject matter, restriction for examination purposes as indicated is proper. Applicants are required under 35 U.S.C. § 121 to elect a single group, including one single peptide, for prosecution on the merits. Applicants are also reminded that the claims should be amended, if necessary, to reflect the election.

Claim Cancellation

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently
5 named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

10 8. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

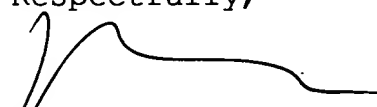
15 9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be
20 directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate
25 their expeditious processing and entry.

30 10. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122,

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respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2001